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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/755,017 | 01/05/2001 | D. Wade Walke | LEX-0115-USA | 4534 |

24231 7590 03/13/2002

LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

| EXAMINER |
|---|
| BUNNER, BRIDGET E |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | 8 |

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/755,017 | Applicant(s) WALKE ET AL. | |
|---|---|---|---|
| | Examiner Bridget E. Bunner | Art Unit 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6, 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Oath/Declaration*

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

### *Specification*

2. The disclosure is objected to because of the following informalities:

2a. Patent applications are referenced in the disclosure (pg 4, lines 17-19). The status of the applications must be updated.

2b. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "NUCLEIC ACID MOLECULE ENCODING A NGPCR PROTEIN".

Appropriate correction is required.

### *Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 1-4 are directed to an isolated nucleic acid molecule comprising at least 24 contiguous bases of nucleotide sequence disclosed in the NGPCR polynucleotide sequence described in SEQ ID NO: 1. The claims recite an isolated nucleic acid molecule comprising the nucleic acid sequence presented in SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes at least fifty contiguous amino acids shown in SEQ ID NO: 2 or a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.

The specification discloses that the human novel G protein-coupled receptor (NGPCR) in the instant application is a novel receptor protein that is expressed in human cells. The specification teaches that NGPCR is a transmembrane protein that falls within the 7 transmembrane family of receptors and modulates signal transduction after the appropriate ligand has bound to the receptor (pg 4, lines 7-12). However, the instant specification does not teach any physiologic ligands or functional characteristics of the NGPCR polypeptide and polynucleotide. The specification does not disclose the nucleotide in the context of a cell or organism or the method by which the nucleic acid sequence for human NGPCR (SEQ ID NO: 2) was determined. Since significant further research would be required of the skilled artisan to determine the function of the claimed polypeptide, the asserted utilities are not substantial. The

specification asserts the following as patentable utilities for the claimed putative polynucleotide (SEQ ID NO: 1):

1) as hybridization probes (pg 9, lines 4-32; pg 13-14)

2) to identify, select, and validate novel molecular targets for drug discovery (pg 10, lines 24-32)

3) in diagnostic assays to identify mutations associated with a particular disease (pg 11, lines 1-10; pg 33-36)

4) to create a genomic library or expression library (pg 15, lines 24-33; pg 16, lines 1-12)

5) to construct a transgenic animal (pg 27, lines 5-32; pg 28, lines 1-29)

Each of these shall be addressed in turn.

*1) as hybridization probes.* This asserted utility is credible but not substantial or specific. Hybridization probes can be designed from any polynucleotide sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*2) to identify, select, and validate novel molecular targets for drug discovery.* This asserted utility is credible but not specific or substantial. Such assays can be performed with any polynucleotide. Additionally, the specification discloses nothing specific or substantial for the molecular targets that can be identified/selected/validated by this method.

*3) in diagnostic assays to identify mutations associated with a particular disease.* This asserted utility is credible but not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose the tissues or cell types the polynucleotide is normally expressed in. The specification also discloses nothing about the

normal levels of expression of the polynucleotide or a specific DNA target. The specification does not disclose any disorders associated with a mutated, deleted, or translocated NGPCR gene (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*4) to create a genomic library or an expression library.* This asserted utility is credible but not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose a specific nucleic acid sequence used to generate the library. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

*5) to construct a transgenic animal.* This asserted utility is credible but not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated NGPCR gene (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify such a disease. The specification discloses nothing about whether the gene will be "knocked in" or "knocked out" or what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4. Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, claims 1-2 are directed to an isolated nucleic acid molecule comprising at least 24 contiguous bases of the nucleotide sequence described in SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes at least 50 contiguous amino acids of the polypeptide sequence shown in SEQ ID NO: 2.

The specification teaches that the invention of the instant application "encompasses nucleotide sequences that encode mutant NGPCRs, peptide fragments of the NGPCR, truncated NGPCRs, and NGPCR fusion proteins" (pg 16, lines 24-27). However, the specification does not teach any variants or fragments of the polynucleotide (SEQ ID NO: 1) of the instant application. The specification also does not teach functional or structural characteristics of the polynucleotide or polypeptide fragments recited in the claims.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to

enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the polynucleotide and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

5. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2 recite an isolated nucleic acid molecule comprising at least 24 contiguous bases of the nucleotide sequence described in SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes at least 50 contiguous amino acids of the polypeptide sequence shown in SEQ ID NO: 2.

The specification teaches a human NGPCR polynucleotide (SEQ ID NO: 1) and a polypeptide encoded by the nucleotides of SEQ ID NO: 1. However, the specification does not teach functional or structural characteristics of the polynucleotides in the context of a cell or organism. The description of one NGPCR polynucleotide species (SEQ ID NO: 1) and one polypeptide species (SEQ ID NO: 2) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all variants and fragments and with at least 24 contiguous bases of SEQ ID NO: 1 or at least 50 contiguous amino acids of SEQ ID NO: 2.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1 and an isolated nucleic acid molecule that encodes the amino acid sequence of SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-2 are rejected as being indefinite because each claim is missing words which render the claims unclear. For example, in claim 1, lines 2-3, the phrase "at least 24 contiguous bases of nucleotide sequence first disclosed in the NGPCR polynucleotide sequence described in SEQ ID NO: 1" is confusing. Also, in claim 2, lines 3-4, the phrase "encodes at least fifty contiguous the amino acids shown in SEQ ID NO: 2" is confusing. (Please note that this issue could be overcome by amending claim 1 to recite, for example: "at least 24 contiguous bases of the nucleotide sequence of SEQ ID NO: 1". Claim 2 could be amended to recite, for example: "encodes at least fifty contiguous amino acids of the amino acid sequence of SEQ ID NO: 2".)

8. Regarding claim 1, the acronym "NGPCR" renders the claims vague and indefinite. Abbreviations should be spelled out in all independent claims for clarity.

9. Claim 2 is rejected as being indefinite. Stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification also does not provide an unambiguous definition for the term. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of **A** X SSC and **B** % SDS at **C**°C"), claim 2 fails to define the metes and bounds of the varying structures of nucleotide sequences recited in the claimed methods.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Accession Number AQ077154, 20 August 1998).

Adams et al. teach at least 24 contiguous bases of the nucleotide sequence of SEQ ID NO: 1 of the instant application (See sequence alignment attached to this Office Action as Appendix A; see nucleotides 182-132 of Adams et al.; see also nucleotides 834-884 of SEQ ID NO: 1 of the instant application.)

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
February 27, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER

Appendix A

```
Title:          US-09-755-017-1
Perfect score:  942
Sequence:       1 atgaattgggtaaatgacag.....tcttcttaatcaagaaataa 942

Scoring table:  IDENTITY_NUC
                Gapop 10.0 , Gapext 1.0

Searched:       11351937 seqs, 5372889281 residues

Total number of hits satisfying chosen parameters:      22703874

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
                 Maximum Match 100%
                 Listing first 45 summaries

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                              ALIGNMENTS

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ACCESSION   AQ077154
VERSION     AQ077154.1  GI:3438338
KEYWORDS    GSS.
SOURCE      human.
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 479)
  AUTHORS   Adams,M.D., Rounsley,S.D., Zhao,S., Bass,S., Linher,K., Golden,K.,
            Berry,K., Granger,D., Suh,E., Wible,C., Shizuya,H., Simon,M. and
            Venter,J.C.
  TITLE     Use of a random human BAC End Sequence Database for Sequence-Ready
            Map Building
  JOURNAL   Unpublished (1998)
COMMENT     Other_GSSs: CIT-HSP-2354D1.TR
            Contact: Mark Adams
            Department of Eukaryotic Genomics
            The Institute for Genomic Research
            9712 Medical Center Dr., Rockville, MD 20850, USA
            Tel: 301 838 0200
            Fax: 301 838 0208
            Email: mdadams@tigr.org
            Clones are available from Research Genetics (info@resgen.com). BAC
            end search page:
            http://www.tigr.org/tdb/humgen/bac_end_search/bac_end_search.html.
            Seq primer: M13-21
            Class: BAC ends.
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BASE COUNT      139 a    100 c    111 g    129 t
ORIGIN

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Qy    537 tgaagtccctgcactgctcaagttatcttgtgttgagacaacagcaaatgaggctgaact 596
          ||||||||||| |||||||||| || |||||||| ||| |||||||||||||||||
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Qy    657 ttttattgtccgagcagtattgaggatacagtctgctgaaggtcgacaaaaagcatttgg 716
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Qy    717 gacatgtggttcccatctaattgtggtgtctctttttatagtacagccgtctctgtgta 776
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Qy    777 cctgcaaccaccttcgcccagctccaaggaccaaggaaagatggtttctctcttctat[redacted]36
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Qy    837 aatcattgcacccatgctgaatccccttatatatacacttaggaacaaggaggtaaagga 896
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